

# General

#### Guideline Title

American Cancer Society lung cancer screening guidelines.

## Bibliographic Source(s)

Wender R, Fontham ET, Barrera E Jr, Colditz GA, Church TR, Ettinger DS, Etzioni R, Flowers CR, Gazelle GS, Kelsey DK, LaMonte SJ, Michaelson JS, Oeffinger KC, Shih YC, Sullivan DC, Travis W, Walter L, Wolf AM, Brawley OW, Smith RA. American Cancer Society lung cancer screening guidelines. CA Cancer J Clin. 2013 Mar-Apr;63(2):106-17. [55 references] PubMed

#### **Guideline Status**

This is the current release of the guideline.

## Recommendations

# Major Recommendations

Clinicians should ascertain the smoking status and smoking history of their patients aged 55 years to 74 years (refer to Table 1 in the original guideline document). Clinicians with access to high-volume, high-quality lung cancer screening and treatment centers should initiate a discussion about lung cancer screening with patients aged 55 years to 74 years who have at least a 30–pack-year smoking history, currently smoke, or have quit within the past 15 years, and who are in relatively good health. Core elements of this discussion should include the following benefits, uncertainties, and harms of screening:

- Benefit: Screening with low-dose computed tomography (LDCT) has been shown to substantially reduce the risk of dying from lung cancer.
- Limitations: LDCT will not detect all lung cancers or all lung cancers early, and not all patients who have a lung cancer detected by LDCT will avoid death from lung cancer.
- Harms: There is a significant chance of a false-positive result, which will require additional periodic testing and, in some instances, an invasive procedure to determine whether or not an abnormality is lung cancer or some non-lung cancer-related incidental finding. Fewer than 1 in 1,000 patients with a false-positive result experience a major complication resulting from a diagnostic workup. Death within 60 days of a diagnostic evaluation has been documented, but is rare and most often occurs in patients with lung cancer.
- Smoking cessation counseling constitutes a high priority for clinical attention for patients who are currently smoking. Current smokers should
  be informed of their continuing risk of lung cancer, and referred to smoking cessation programs. Screening should not be viewed as an
  alternative to smoking cessation.
- Eligible patients should make the screening decision together with their health care provider. Helping individuals to clarify their personal values can facilitate effective decision-making:
  - Individuals who value the opportunity to reduce their risk of dying from lung cancer and who are willing to accept the risks and costs associated with having an LDCT and the relatively high likelihood of the need for further tests, even tests that have the rare but real

- risk of complications and death, may opt to be screened with LDCT every year.
- Individuals who place greater value on avoiding testing that carries a high risk of false-positive results and a small risk of complications, and who understand and accept that they are at a much higher risk of death from lung cancer than from screening complications, may opt not to be screened with LDCT.
- Clinicians should not discuss lung cancer screening with LDCT with patients who do not meet the above criteria. If lung cancer screening is
  requested, these patients should be informed that at this time, there is too much uncertainty regarding the balance of benefits and harms for
  individuals at younger or older ages and/or with less lifetime exposure to tobacco smoke and/or with sufficiently severe lung damage to
  require oxygen (or other health-related National Lung Screening Trial [NLST] exclusion criteria), and therefore screening is not
  recommended.
- Adults who choose to be screened should follow the NLST protocol of annual LDCT screening until they reach age 74 years.
- Chest x-rays (CXR) should not be used for cancer screening.
- Wherever possible, adults who choose to undergo lung screening preferably should enter an organized screening program at an institution with expertise in LDCT screening, with access to a multidisciplinary team skilled in the evaluation, diagnosis, and treatment of abnormal lung lesions. If an organized, experienced screening program is not accessible, but the patient strongly wishes to be screened, they should be referred to a center that performs a reasonably high volume of lung computed tomography (CT) scans, diagnostic tests, and lung cancer surgeries. If such a setting is not available and the patient is not willing or able to travel to such a setting, the risks of cancer screening may be substantially higher than the observed risks associated with screening in the NLST, and screening is not recommended. Referring physicians should help their patients identify appropriate settings with this expertise.
- At this time, very few government or private insurance programs provide coverage for the initial LDCT preformed for the indication of lung cancer screening. Clinicians who decide to offer screening bear the responsibility of helping patients determine if they will have to pay for the initial test themselves and to help the patient know how much they will have to pay. In light of the firm evidence that screening high-risk individuals can substantially reduce death rates from lung cancer, both private and public health care insurers should expand coverage to include the cost of annual LDCT screening for lung cancer in appropriate high-risk individuals.

	individuals can substantially reduce death rates from lung cancer, both private and public health care insurers should expand coverage to
	include the cost of annual LDCT screening for lung cancer in appropriate high-risk individuals.
Clin	ical Algorithm(s)

# Scope

Disease/Condition(s)

Lung cancer

None provided

Guideline Category

Diagnosis

Screening

# Clinical Specialty

Family Practice

Internal Medicine

Nursing

Oncology

Pulmonary Medicine

#### **Intended Users**

Advanced Practice Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To provide clinicians and the public with guidance about screening for lung cancer, and specii-cally to address:

- Who is and who is not a candidate for lung cancer screening
- What is known about the beneïts, limitations, and harms associated with lung cancer screening
- The importance and key elements of informed and shared decision-making prior to making a decision to undergo lung cancer screening
- Specific recommendations about the screening process and the importance of smoking cessation for current smokers

## **Target Population**

Patients aged 55 years to 74 years who have at least a 30-pack-year smoking history, currently smoke, or have quit within the past 15 years, and who are in relatively good health

#### **Interventions and Practices Considered**

- 1. Low-dose computed tomography (LDCT)
- 2. Chest x-ray (CXR) (not recommended)
- 3. Smoking cessation counseling

## Major Outcomes Considered

- Lung cancer-specific or all-cause mortality
- Nodule detection rate
- · Frequency of additional imaging
- Frequency of invasive diagnostic procedures (e.g., needle or bronchoscopic biopsy, surgical biopsy, or surgical resection)
- Anxiety associated with abnormal testing results
- Complications from the evaluation of suspected lung cancer
- Investigation of incidental findings outside the lung field
- Rate of smoking cessation or reinitiation

# Methodology

#### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

# Description of Methods Used to Collect/Select the Evidence

Following the announcement of the National Lung Screening Trial (NLST) results in late 2010, the American Cancer Society (ACS) joined with the American College of Chest Physicians, the American Society of Clinical Oncology, and the National Comprehensive Cancer Network (NCCN) to produce a systematic review of the evidence related to lung cancer screening with low-dose computed tomography (LDCT) (see the "Availability of Companion Documents" field).

The systematic review focused on 4 key questions:

- What are the potential benefits of screening individuals at high risk of developing lung cancer using LDCT?
- What are the potential harms of screening individuals at high risk of developing lung cancer using LDCT?
- Which groups are likely to benefit or not benefit?
- In what setting is screening likely to be effective?

The literature search was developed and conducted by an experienced systematic reviewer using MEDLINE (Ovid: January 1996 to April 8, 2012), EMBASE (Ovid: January 1996 to April 8, 2012), and the Cochrane Library (April 20, 2012). Additional citations were gleaned from the reference lists of related papers and review articles. The literature search included Medical Subject Headings (MeSH) and Emtree headings and related text and keyword searches in a manner that combined terms related to lung cancer, population screening, and low-dose computed tomography (LDCT) (see eAppendix 1 of the systematic review; see the "Availability of Companion Documents" field). The search was limited to published data only.

Studies were eligible for inclusion if they involved either a randomized controlled trial (RCT) using LDCT screening for lung cancer in one intervention group or a noncomparative cohort study of LDCT screening, provided they reported at least 1 of the following outcomes: lung cancer—specific or all-cause mortality, nodule detection rate, frequency of additional imaging, frequency of invasive diagnostic procedures (e.g., needle or bronchoscopic biopsy, surgical biopsy, surgical resection), complications from the evaluation of suspected lung cancer, or the rate of smoking cessation or reinitiation. For lung cancer—specific and all-cause mortality endpoints, only RCT data were considered eligible for inclusion; for other endpoints, data from the LDCT group of both RCTs and cohort studies were included.

Exclusion criteria covered studies that only assessed screening among participants with risk factors other than smoking (e.g., asbestos), those not published in English, and meta-analysis or case series reports of outcomes only among patients diagnosed with lung cancer. The exclusion criteria were determined a priori and guided whether data identified by the systematic literature review were judged to have been reported in a manner appropriate for inclusion. Articles were selected and data were extracted independently by a minimum of 2 reviewers. At the point of abstract review, if 1 of 2 reviewers indicated that a citation may be relevant, the full-text article was retrieved. After full text review, if there was a discrepancy among the 2 reviewers, a third reviewer determined eligibility, and the reviewers came to consensus. In addition, the third reviewer also verified that articles deemed ineligible did not meet eligibility criteria.

#### Number of Source Documents

A total of 591 citations were identified by the search strategy, which yielded 8 randomized controlled trials (RCTs) and 13 cohort studies.

## Methods Used to Assess the Quality and Strength of the Evidence

**Expert Consensus** 

# Rating Scheme for the Strength of the Evidence

Not applicable

# Methods Used to Analyze the Evidence

Systematic Review

# Description of the Methods Used to Analyze the Evidence

In developing this guideline, particular weight was given to the National Lung Screening Trial (NLST) based on its larger study size.

The systematic review panel (see the "Availability of Companion Documents" field) was divided into evidence review subcommittees, focusing on 4 key questions.

- 1. What are the potential benefits of screening individuals at elevated risk of developing lung cancer using low-dose computed tomography (LDCT)?
- 2. What are the potential harms of screening individuals at elevated risk of developing lung cancer using LDCT?
- 3. Which groups are most likely to benefit or not benefit from screening?
- 4. In what setting is screening likely to be effective?

Data Extraction

Critical appraisal using predefined criteria was conducted on individual studies and the overall body of evidence. Differences in data extracted by reviewers were adjudicated by consensus.

#### Methods Used to Formulate the Recommendations

**Expert Consensus** 

## Description of Methods Used to Formulate the Recommendations

Not stated

## Rating Scheme for the Strength of the Recommendations

Not applicable

# Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### Method of Guideline Validation

Not stated

# Description of Method of Guideline Validation

Not applicable

# **Evidence Supporting the Recommendations**

# Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

# Benefits/Harms of Implementing the Guideline Recommendations

#### Potential Benefits

- Screening with low-dose computed tomography (LDCT) has been shown to substantially reduce the risk of dying from lung cancer.
- Evidence from noncomparative studies suggests that an additional benefit of LDCT screening may be a positive effect on smoking cessation among smokers who undergo screening and are counseled to quit smoking.
- Detection by computed tomography (CT) of incidental findings outside of the lung

#### Potential Harms

- Significant chance of a false-positive result, which will require additional periodic testing and, in some instances, an invasive procedure to
  determine whether or not an abnormality is lung cancer or some nonlung cancer-related incidental finding. Fewer than 1 in 1000 patients
  with a false-positive result experience a major complication resulting from a diagnostic workup. Death within 60 days of a diagnostic
  evaluation has been documented, but is rare and most often occurs in patients with lung cancer.
- Harms associated with low-dose computed tomography (LDCT) screening include anxiety associated with abnormal testing results, additional imaging tests and biopsy procedures associated with false-positive results, and investigations for incidental findings outside of the lung field; in rare instances, serious harms, including hospitalizations and death, can result from diagnostic evaluations in patients with and without lung cancer.
- There are concerns about radiation exposure from repeat LDCT screening examinations and higher-dose diagnostic evaluations.
- To the degree that some overdiagnosis occurs in lung cancer screening, it represents a harm of screening since an overdiagnosed cancer can be expected to result in overtreatment.

See the "Limitations and Harms" section in the original guideline document for more information.

# **Qualifying Statements**

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- At this time, there is sufficient evidence to support screening provided that the patient has undergone a thorough discussion of the benefits, limitations, and risks, and can be screened in a setting with experience in lung cancer screening.
- Adults seeking testing for early lung cancer detection must be informed that screening will not detect all lung cancers, and the detection of a
  cancer by low-dose computed tomography (LDCT) does not guarantee that death from lung cancer will be avoided.
- While the degree to which the average imaging facility in the United States can deliver the level of care that was delivered in the National
  Lung Screening Trial (NLST) is not known, it is expected that the level of preparedness to deliver high-quality screening and follow-up is
  variable across the nation.
- Smoking cessation counseling constitutes a high priority for clinical attention for patients who are currently smoking. Current smokers should
  be informed of their continuing risk of lung cancer and referred to smoking cessation programs. Screening should not be viewed as an
  alternative to smoking cessation.

# Implementation of the Guideline

# Description of Implementation Strategy

An implementation strategy was not provided.

# Implementation Tools

Patient Resources

Staff Training/Competency Material

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

#### IOM Care Need

Living with Illness

Staying Healthy

#### **IOM Domain**

Effectiveness

Patient-centeredness

# Identifying Information and Availability

# Bibliographic Source(s)

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# Adaptation

Not applicable: The guideline was not adapted from another source.

#### Date Released

2013 Mar-Apr

# Guideline Developer(s)

American Cancer Society - Disease Specific Society

# Source(s) of Funding

American Cancer Society

#### Guideline Committee

Not stated

# Composition of Group That Authored the Guideline

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#### Financial Disclosures/Conflicts of Interest

Richard Wender, MD; Elizabeth T. H. Fontham, MPH, DrPH; Ermilo Barrera, Jr, MD; Graham A. Colditz, MD, DrPH; Timothy R. Church, PhD; David S. Ettinger, MD; Ruth Etzioni, PhD; Samuel J. LaMonte, MD; James S. Michaelson, PhD; Kevin C. Oeffinger, MD; Ya-Chen Tina Shih, PhD; Daniel C. Sullivan, MD; William Travis, MD; Louise Walter, MD; Andrew M. D. Wolf, MD; Otis W. Brawley, MD; and Robert A. Smith, PhD, have no conflicts of interest to disclose.

Christopher R. Flowers, MD, has received consulting fees from Celgene Corporation; Spectrum; Seattle Genetics, Inc; OptumRx; Clinical Care Options; and Education Concepts Group. He has performed contracted research for Millennium Pharmaceuticals, Celgene Corporation, Spectrum, Gilead Pharmaceuticals, and Janssen Pharmaceuticals.

G. Scott Gazelle, MD, MPH, PhD, is a consultant to GE Healthcare. His work for GE Healthcare is not directly related to this article.

Douglas K. Kelsey, MD, PhD, is employed by Eli Lilly and Company.

#### Guideline Status

This is the current release of the guideline.

# Guideline Availability

Electronic copies: Available from the CA: A Cancer Journal for Clinicians Web site	
Print copies: Available from the American Cancer Society, 250 Williams St., Suite 600, Atlanta, GA 30303; We	eb site: www.cancer.c

# Availability of Companion Documents

The following is available:

Bach PB, Mirkin JN, Oliver TK, Azzoli CG, Berry DA, Brawley OW, Byers T, Colditz GA, Gould MK, Jett JR, Sabichi AL, Smith-
Bindman R, Wood DE, Qaseem A, Detterbeck FC. Benefits and harms of CT screening for lung cancer. A systematic review. JAMA
2012 Jun 13;308(22):2418-29. Electronic copies: Available in Portable Document Format (PDF) from the Journal of the American
Medical Association Web site
n addition, continuing medical education and continuing nursing education activities are available in the original guideline document.
Patient Resources

#### Patient Resources

The following is available:

• Testing for lung cancer in people at high risk. Patient page. CA: Cancer J Clin 2013 Mar-Apr;63(2):118-9. Electronic copies: Available in Portable Document Format (PDF) from the CA: A Cancer Journal for Clinicians Web site

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#### NGC Status

This NGC summary was completed by ECRI Institute on May 23, 2013. The information was verified by the guideline developer on June 20, 2013.

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